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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

J M SMITH CORPORATION d/b/a SMITH DRUG COMPANY, on behalf of itself and all others similarly situated, Plaintiff, v. HETERO USA INC.; HETERO LABS LTD.; HETERO DRUGS LTD.; TORRENT PHARMACEUTICALS LTD.; TORRENT PHARMA INC.; ASCEND LABORATORIES, LLC; ALKEM LABORATORIES LTD.; INDCHEMIE HEALTH SPECIALTIES PRIVATE LTD.; GLENMARK GENERICS INC., USA; GLENMARK GENERICS LTD.; GLENMARK PHARMACEUTICALS S.A.; AMERIGEN PHARMACEUTICALS, INC.; AMERIGEN PHARMACEUTICALS, LTD.; WATSON LABORATORIES, INC. (NV); WATSON LABORATORIES, INC. (DE); WATSON LABORATORIES, INC. (NY); WATSON LABORATORIES, INC. (CT); WATSON PHARMA, INC.; WATSON PHARMACEUTICALS INC.; ACTAVIS, INC.; TEVA PHARMACEUTICAL INDUSTRIES LTD., AND TEVA PHARMACEUTICALS USA, INC. Defendants.	Case No. 20-cv-7110-LJL **FIRST AMENDED CLASS ACTION COMPLAINT** JURY TRIAL DEMANDED

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Plaintiff J M Smith Corporation d/b/a Smith Drug Company ("Plaintiff"), on behalf of itself and all others similarly situated, brings this Class Action Complaint against Hetero USA Inc., Hetero Labs Ltd., and Hetero Drugs Ltd. (collectively "Hetero"); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent"); Ascend Laboratories, LLC ("Ascend"); Alkem Laboratories Ltd. ("Alkem"); Indchemie Health Specialties Private Ltd. ("Indchemie"); Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals S.A. (collectively, "Glenmark"); Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. (collectively "Amerigen"); and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., Watson Pharmaceuticals Inc., Actavis, Inc., Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Watson") (together, Hetero, Torrent, Alkem, Indchemie, Glenmark, Amerigen, and Watson are "Defendants") for Defendants' violations of the antitrust laws concerning the pharmaceutical drug Bystolic® (nebivolol hydrochloride) ("Bystolic"). Based on (a) personal knowledge, (b) the investigations of counsel, and (c) information and belief, Plaintiff alleges:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages and declaratory and injunctive relief arising out of the Defendants' unlawful delay of their generic substitutes for the branded drug Bystolic, otherwise known as nebivolol hydrochloride or nebivolol HCl, a "beta blocker" used to treat high blood pressure. Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Forest Laboratories, LLC, and Forest Laboratories Ireland Ltd. and its successors[1] (collectively, "Forest") manufacture the brand version of Bystolic, which is one of Forest's key drugs, delivering nearly $1 billion in United States annual sales.[2] Although would-

[1] These include AbbVie, Inc. ("AbbVie"); and Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, "Allergan").

[2] Glenmark Pharmaceuticals receives ANDA approval for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg, https://www.glenmarkpharma.com/sites/default/files/Glenmark-receives-

be generic manufacturers began applying with the United States Food and Drug Administration (the "FDA") to market generic nebivolol HCl on December 17, 2011,[3] no generic competitor has entered or will enter until September 17, 2021.

2. The only material difference between generic and brand name drugs is their price – generics are typically at least 50-80% less expensive when there are multiple generic competitors on the market. As a result, generics constitute both (a) an opportunity for drug purchasers to obtain enormous cost savings; and (b) a serious threat to the monopoly power and profits of the manufacturer of the corresponding brand name drug. Indeed, AB-rated generics typically take 80% or more of the sales of a drug molecule from the brand name product within six months of generic entry. These extremely rapid erosion rates of the brand manufacturer's sales are due in large part to a unique feature of the pharmaceutical industry called drug substitution laws, which permit (and in many states require) dispensing pharmacies to substitute available AB-rated generic drugs for a brand drug unless the prescribing physician specifically orders otherwise.

3. Acutely aware of these realities, Defendants, who are generic drug manufacturers, each entered into unlawful reverse-payment deals (also known as "pay for delay" deals) with Forest. From October 2012 through November 2013, Defendants entered into these serial deals pursuant to which each one (1) agreed not to compete with Forest or enter the market with its generic version of Bystolic prior to September 17, 2021, unless another Defendant entered the market earlier; and in exchange (2) received "side-deals," and cash payments from Forest, the precise amounts of which have not been publicly disclosed except that, on information and belief, they each exceed $15,000,000 in value. This illegal collusion and unreasonable restraint of trade in the market for nebivolol HCl has continued, all at the expense of purchasers. Every

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ANDA-approval-for-Nebivolol-Tablets%2C2.5-mg%2C5-mg%2C10-mg-and-20-mg.pdf, May 29, 2017.

[3] *See, e.g.*, 11/27/2015 Letter from Food and Drug Administration ("FDA") to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf.

month of delayed generic competition has allowed Forest to unlawfully maintain many millions of dollars in monopoly profits from Bystolic without generic competition and allowed the Defendants to share in those profits by pocketing large and unjustified payments from Forest for agreeing to delay bringing generic nebivolol HCl to market.

4. Forest submitted two patents for listing in the FDA Orange Book under the new drug application for Bystolic: U.S. Patent Nos. 6,545,040 (the "'040 Patent") and 5,759,580 (the "'580 Patent"). Beginning on December 17, 2011,[4] after the Defendants became the first generic manufacturers to seek approval from the FDA to market generic Bystolic, Forest sued each of them, accusing them of infringing the '040 Patent. Forest did not assert the '580 Patent against the Defendants. These suits, filed in mid-March 2012, automatically triggered stays of FDA approval of the generic products (meaning that regardless of the merits of the patent infringement actions, the FDA could not grant final approval to any of the Defendants to launch a generic version of Bystolic before June 18, 2015 absent an earlier favorable decision for the Defendants or a dismissal of the actions). And foreclosing the Defendants from launching also has foreclosed all other generic manufacturers; as the first manufacturers to file for approval for generic Bystolic, the Defendants are eligible to share 180 days of market exclusivity, free from competition from other generic manufacturers (other than a generic marketed or authorized to be marketed by Forest, also known as an "authorized generic"), once they actually launch their generic versions of Bystolic.

5. Between March 2012 through November 2013, while the stays were in effect, the Defendants fought the patent infringement suits and prepared to bring their generic Bystolic products to market to compete with Forest's branded Bystolic. At least six of the Defendants

[4] *See, e.g.*, 11/27/2015 Letter from FDA to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf; 5/27/2017 Letter from FDA to Glenmark, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf; 6/24/2015 Letter from FDA to Alkem, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf.

would have been ready to launch well before September 17, 2021, as each received final FDA approval to do so as set forth in the table below:

Manufacturer	ANDA No.	Final Approval Date
Amerigen	203659	4/16/15
Watson	203683	11/27/15
Alkem	203741	6/24/15
Glenmark	203821	5/25/17
Indchemie	203828	7/29/15
Torrent	203966	3/2/18

6. The Defendants would have succeeded in the patent litigation because the '040 Patent was weak. The '040 Patent litigation likely would have concluded by mid-2015, including all appeals. The Defendants would have won and launched by the later of: (a) the June 2015 expiration of the litigation stay, or (b) the date their Abbreviated New Drug Applications ("ANDAs") were finally approved. But rather than compete with Forest as early as June 2015 and trigger the predictable reduction in Bystolic brand sales and revenues such competition would cause, each Defendant agreed to accept a reverse payment from Forest to stay off the market until September 21, 2021.

7. The side-deals that each Defendant agreed to were intended to shield Forest from the risk of competition, and to allow each Defendant to share in Forest's monopoly profits. Defendants readily accepted these exclusionary side-deals to quit the patent fight.

8. On February 18, 2014 Actavis PLC and Forest announced an equity and cash merger.[5] On March 1, 2014 Forest's outside lawyers at Weil, Gotshal & Manges LLP were reviewing Forest's documents as part of their "work on the Actavis merger agreement."[6] On March 4, 2014, Forest's outside lawyers informed Forest in-house counsel Eric Agovino via

[5] *See* Actavis to Acquire Forest Laboratories, Inc. for ~$25 Billion in an Equity and Cash Transaction, https://www.businesswire.com/news/home/20140218005877/en/Actavis-Acquire-Forest-Laboratories-25-Billion-Equity.

[6] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-44 at 332).

email (the "Agovino email") that "[b]efore we engage in any discussions with the FTC . . . we think it would be prudent for us to review all of the Bystolic settlement and licensing agreements ***as well as the side agreements with those generic companies***."[7] Agovino replied:

> We entered into settlement agreements with the following defendants:
>
> 1) Hetero
>
> 2) Torrent
>
> 3) Alkem
>
> 4) Indchemie
>
> 5) Glenmark
>
> 6) Amerigen
>
> 7) Actavis [Watson's successor]
>
> ***All had side-deals*** (one was struck with Alkem, which is a related company with Indchemie).[8]

9. Forest's Agreement and Plan of Merger with Actavis PLC (the "Merger Agreement"), dated February 17, 2014, provides additional details. Specifically, in the Merger Agreement Forest disclosed its "material contracts," which are defined to include "any Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of $15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied."[9]

10. Forest listed each of the side-deals as a "material contract" "in connection with the settlement of BYSTOLIC patent dispute."

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[7] *Id*. (emphasis added).

[8] *Id*. (emphasis added).

[9] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

11. Thus Forest has described each of the side-deals set forth below as a "material contract," *i.e.*, it was a "Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of $15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied." The respective contracts are set forth below.

12. **Hetero:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012 . . . together with the FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute."[10]

13. **Torrent:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012 . . . together with the PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[11]

14. **Alkem/Indchemie:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute. AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT was executed on January 9, 2013" and "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and

[10] *Id*. at 179

[11] *Id*.

Indchemie Health Specialties Private Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd, Indchemie Health Specialties Private Ltd, and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute."[12]

15. **Glenmark:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012 . . . together with the COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[13]

16. **Amerigen:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013 . . . together with the BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute."[14]

17. **Watson:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013 . . . together with (a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between Actavis, Inc. and Moksha8, Inc. dated November 4, 2013, in

[12] *Id.*

[13] *Id.*

[14] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 180).

connection with the settlement of BYSTOLIC patent dispute."[15]

18. Forest listed the side-deals in the Merger Agreement because, on information and belief, they "involve payments after the date [t]hereof of consideration in excess of $15,000,000."

19. As Forest publicly acknowledged in the Agovino email, and in the Merger Agreement, the side-deals were entered into as part and parcel of the Defendants' patent settlement agreements with Forest in the Bystolic patent litigation.

20. In addition to the consideration each Defendant accepted from Forest in the form of a side-deal, Forest "agreed to reimburse certain of the Settling Defendants' legal costs in connection with the patent litigation."[16]

21. Forest also disclosed that its settlement agreements with the Defendants "provide[d] a license to each of the Settling Defendants that will permit them to launch their respective generic versions of Bystolic as of the date that is the later of (a) three calendar months prior to the expiration of the '040 patent, including any extensions and/or pediatric exclusivities or (b) the date that each Settling Defendant receives final FDA approval of its ANDA, ***or earlier in certain circumstances***."[17] The bolded language typically refers to what is known as a "contingent launch provision" ("CLP"), or an "acceleration clause." CLPs ensure a settling generic that it will not be competitively disadvantaged should a later settling generic negotiate an earlier licensed entry date or otherwise come to market earlier: pursuant to the CLPs the entry date may be "accelerated" permitting the settling generic to enter the market at the same time as any of its competitors. CLPs ensure settling generic ANDA filers that, if any other ANDA filer

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[15] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 180).

[16] https://www.sec.gov/Archives/edgar/data/38074/000003807413000014/forest10k2013.htm at 29.

[17] *Id*. (emphasis added).

somehow makes it to market before the agreed-upon licensed entry date, that ANDA filer's licensed entry date would be accelerated so that it could launch at the same time.

22. When CLPs are used, they generally operate the same way in each ANDA filer's settlement agreement. Under a CLP, the first ANDA filer obtains protection from other first ANDA filers by agreeing to delay the launch of its generic product from the date of settlement until a date certain (here, exactly three months before the expiration of the '040 Patent),[18] but *if and only if* all other first ANDA filers follow suit.

23. By entering into their respective agreements, each Defendant and Forest ensured that, without regard to the strength of Defendants' challenges to the '040 Patent, Bystolic would have no generic competitors and Forest would maintain patent-generated monopoly profits until at least September 17, 2021, and none of the Defendants would come to market earlier.

24. Reverse-payment agreements like the side-deals in this case delay the entry date for generic drug products beyond the date when competition would ensue in the absence of a reverse payment. As the Third Circuit Court of Appeals put it, "when the parties' settlement includes a [payment], the generic also presumably agrees to an early entry date [before patent expiration] that is later than it would have otherwise accepted." *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015). Thus, without the ability to offer or accept an unlawful reverse payment, Forest and each Defendant would have instead agreed upon earlier licensed entry dates for generic versions of Bystolic. And, because of the CLPs, if *just one* Defendant did not take an unlawful payment, and instead insisted on an earlier entry date untainted by a side-deal, *every other* Defendant would enter on the same earlier date.

25. Accordingly, each Defendant had the power to either delay or accelerate generic entry and was therefore the proximate and foreseeable cause of injury to Plaintiff and the proposed Class. Even if they acted independently of one another, Defendants jointly and severally contributed to an indivisible harm, because each of their reverse payment agreements

[18] *Id.*

caused delay of generic versions of Bystolic in a manner for which there is no reasonable basis for division according to the contribution of each Defendant.[19]

26. In sum, but for the anticompetitive reverse payments, the Defendants would have launched their generic products earlier either: (a) at risk;[20] (b) upon prevailing against Forest in the underlying patent litigation; or (c) via lawful settlement agreements providing for earlier negotiated entry dates untainted by the delay caused by the unlawful reverse payments.

27. Had any of the above scenarios played out – as would have occurred absent the unlawful reverse payments – Plaintiff and the Class it seeks to represent (defined below) would have paid substantially less for nebivolol HCl.

28. Defendants' conduct was designed to, did, and continues to: (a) delay the entry of less expensive, AB-rated generic versions of Bystolic; (b) fix, raise, maintain or stabilize the price of nebivolol HCl; and (c) allocate 100% of the United States market for nebivolol HCl to Forest until three months before expiration of the '040 Patent.

29. Defendants' conspiracies with Forest – as distinguished from growth or development as a consequence of a legally-obtained valid patent, other legally-obtained market exclusivity, a superior product, business acumen, or historical accident – constituted willful exclusionary conduct that enabled Forest to maintain monopoly power in the nebivolol HCl market.

30. As alleged below, Defendants' conspiracies violated Sections 1 and 2 of the Sherman Act, injuring Plaintiff and the Class of direct purchasers it seeks to represent (as defined below) and causing them to pay overcharges.

II. PARTIES

31. Plaintiff J M Smith Corporation, d/b/a Smith Drug Company is a corporation

[19] *See, e.g.*, *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 262 n.29 (3d Cir. 2016).

[20] An "at risk" launch occurs when a generic has received final approval from the FDA to market its product but the patent infringement litigation is continuing, and therefore the generic may be "at risk" of incurring infringement damages if it enters the market but later loses the patent litigation.

organized under the laws of the State of South Carolina and is located at 9098 Fairforest Road, Spartanburg, South Carolina 29301.

32. Defendant Watson Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

33. Defendant Watson Laboratories, Inc. (NV) is a corporation operating under the name Watson Laboratories, Inc. and is organized and existing under the laws of the State of Nevada. Watson Laboratories, Inc. (NV) has places of business at 132 Business Center Drive, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

34. Defendant Watson Laboratories, Inc. (DE) is a corporation operating under the name Watson Laboratories, Inc. and is organized and existing under the laws of the State of Delaware. Watson Laboratories, Inc. (DE) has places of business at 311 Bonnie Circle, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

35. Defendant Watson Laboratories, Inc. (NY) is a corporation operating under the name Watson Laboratories, Inc. and is organized and existing under the laws of the State of New York. Watson Laboratories, Inc. (NY) has places of business at 311 Bonnie Circle, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

36. Defendant Watson Laboratories, Inc. (CT) is a corporation operating under the name Watson Laboratories, Inc. and is organized and existing under the laws of the State of Connecticut. Watson Laboratories, Inc. (CT) has places of business at 131 West St. Danbury, CT, 311 Bonnie Circle, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

37. Watson Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Nevada, having places of business at 311 Bonnie Circle, Corona, CA 92880 and 360 Mount Kemble Avenue, Morristown, NJ 07962, and its corporate headquarters at Morris Corporation Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

38. On information and belief, Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), and Watson Pharma, Inc. are wholly-owned subsidiaries of Watson Pharmaceuticals, Inc. On information and belief Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. have officers and directors in common.

39. On information and belief, Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), and Watson Pharma, Inc. act as agents of Watson Pharmaceuticals, Inc.

40. Actavis, Inc., is a corporation organized and existing under the laws of the State of Nevada with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Watson purchased Actavis, Inc. on October 31, 2012[21] and the combined companies assumed the Actavis name.[22] On information and belief, both Watson and Actavis are signatories to the unlawful reverse payment agreement resolving the nebivolol HCl patent litigation between Forest and Watson.

41. Defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation with a principal place of business at 5 Basel St., Petach Tikva, Israel 4951033.

42. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

43. Teva Pharmaceutical Industries Ltd. purchased Watson, at the time known as Actavis, on July 26, 2015.[23] As part of the purchase, Teva agreed to adopt "all Liabilities and

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[21] https://www.biospace.com/article/releases/watson-pharmaceuticals-inc-completes-actavis-acquisition-/

[22] https://www.prnewswire.com/news-releases/watson-announces-new-name----actavis----for-global-operations-176683401.html

[23] Master Purchase Agreement dated as of July 26, 2015 by and between Allergan PLC and Teva Pharmaceutical Industries, Ltd., *available at* https://www.sec.gov/Archives/edgar/data/1578845/000156459015006357/agn-ex22_652.htm.

Claims" of Actavis.[24] On information and belief, Teva Pharmaceuticals USA, Inc. is Teva Pharmaceutical Industries Ltd.'s wholly owned subsidiary, and is responsible for distributing (or forbearing from distributing pursuant to the challenged Watson settlement agreement and side deal) generic Bystolic on behalf of Teva Pharmaceutical Industries Ltd.

44. Defendant Torrent Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Off. Ashram Road, Ahmedabad - 380 009, Gujarat, India.

45. Defendant Torrent Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, MI 49009. On information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd. On information and belief, Torrent Pharma Inc. acts as the agent of Torrent Pharmaceuticals Ltd.

46. Defendant Amerigen Pharmaceuticals Ltd. is a Chinese company having places of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816 and No. 58, Qunxing Yi Road, Suzhou Industrial Park, 215006, China.

47. Defendant Amerigen Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816. On information and belief, Amerigen Pharmaceuticals Inc. is a wholly-owned subsidiary of Amerigen Pharmaceuticals Ltd. On information and belief, Amerigen Pharmaceuticals Inc. acts as the agent of Amerigen Pharmaceuticals Ltd.

48. Defendant Glenmark Generics Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, NJ 07430. Glenmark Generics Inc. is the same entity as Glenmark Generics Inc., USA. To the extent Glenmark Generics Inc. is an entity separate and apart from Glenmark Generics

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[24] *Id*. at 35.

Inc., USA, any allegations in this Complaint relating to Glenmark Generics Inc., USA shall apply equally to Glenmark Generics Inc.

49. Defendant Glenmark Generics Ltd. is an Indian company having a place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

50. Defendant Glenmark Pharmaceuticals S.A. is a company organized and existing under the laws of Switzerland, with a principal place of business at 2nd Floor, Swisscom Building, Rue de la Maladiere 23, Neuchâtel, 2000, Switzerland.

51.

52. Defendant Hetero Labs Ltd. is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate, Sanathnagar, Hyderabad - 500018 Andhra Pradesh, India.

53. Defendant Hetero Drugs Ltd. is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate, Sanathnagar, Hyderabad - 500018 Andhra Pradesh, India.

54. Defendant Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. On information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Ltd. On information and belief, Hetero USA Inc. acts as the agent of Hetero Labs Ltd. and Hetero Drugs Ltd.

55. Defendant Indchemie Health Specialties Private Ltd. is an Indian company having a place of business at 510, Shah & Nahar Industrila Estate, Dr. E. Moses Road, Worli-Mumbai 400018, India.

56. Defendant Alkem Laboratories Ltd. is an Indian company having a place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

57. Defendant Ascend Laboratories, LLC (“Ascend”) is a corporation organized and

existing under the laws of the State of New Jersey, with its principal place of business at 339 Jefferson Road, Suite 101 Parsippany, NJ, 07054. On information and belief, Ascend is a United States agent of Alkem. Ascend is a wholly owned subsidiary of Alkem. On information and belief, Ascend is operationally controlled by Alkem. Ascend is in the business of marketing, distributing, and selling, in the State of New York and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Alkem. On information and belief, since Alkem's acquisition of Ascend in 2010, Alkem has marketed and sold its generic drugs in the United States primarily through Ascend. On information and belief, but for the services Ascend provides Alkem in New York and throughout the United States, Alkem would have to undertake those services on its own. On information and belief, Alkem will market its delayed generic version of Bystolic through Ascend and Ascend will sell generic Bystolic at supracompetitive prices, making Ascend a participant in the conspiracy with Alkem and Forest alleged herein. On information and belief, at Alkem's direction, Ascend has agreed that it will not market or distribute Alkem's generic version of Bystolic until September 17, 2021 when it otherwise would have done so earlier.

58. All of the Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants.

III. JURISDICTION AND VENUE

59. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the Class (defined below) resulting from Defendants' conspiracies to restrain trade in the United States market for nebivolol HCl. The Court has subject matter jurisdiction under 28 U.S.C. §§

1331, 1337(a), 1407, 15 U.S.C. § 15 and 15 U.S.C. § 22.

60. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a) and 22, and 28 U.S.C. §§ 1391(b), (c), and (d) because during the class period, Defendants resided, transacted business, were found, or had agents in the United States and in this District, and a substantial portion of the alleged conduct that affected interstate trade and commerce discussed herein has been carried out in the United States and in this District.

61. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

62. During the class period, Forest manufactured, sold and shipped Bystolic at supracompetitive prices in a continuous and uninterrupted flow of interstate commerce. Defendants' anticompetitive conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

63. During the class period, each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their scheme.

64. This Court has personal jurisdiction over each Defendant, because each Defendant has – throughout the United States and including in this District – transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy. Each Defendant's conspiracy has been directed at, and has had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

65. This Court has personal jurisdiction over each Defendant under 15 U.S.C. § 22 because each Defendant transacts business in this District. This Court has specific personal jurisdiction under CPLR § 302(a) over all Defendants because Forest, from its then-principal place of business in New York, NY, did all of the following: (a) entered into the agreements containing the challenged reverse payments to each Defendant; (b) made the promised reverse

payments to each Defendant; (c) enforced each Defendant's agreement to delay entry of its generic Bystolic in consideration for those reverse payments; (d) sold branded Bystolic at supracompetitive prices made possible by the generic delay those reverse payments to each Defendant purchased; and (e) earned as a result of those sales ill-gotten gains from the delay in generic Bystolic competition that those reverse payments to each Defendant purchased. Moreover, on information and belief, some or all of the agreements containing the challenged reverse payments direct application of New York law and select a New York forum. Personal jurisdiction also lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary defendants.

IV. CLASS ACTION ALLEGATIONS

66. Plaintiff brings this action on behalf of itself and, under Federal Rule of Civil Procedure 23(a), (b)(2) and (b)(3), as a representative of a class of direct purchasers (the "Class" or "Direct Purchaser Class") defined as follows:

> All persons or entities in the United States, including its territories, possessions, and the Commonwealth of Puerto Rico, who purchased brand Bystolic directly from Forest or generic Bystolic directly from any drug manufacturer at any time from July 9, 2016 until the effects of Defendants' conduct cease (the "Class Period"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

67. Members of the Direct Purchaser Class are so numerous and/or geographically dispersed that joinder is impracticable. While the exact number of Class members is unknown to Plaintiff at this time, it is believed to be sufficiently numerous. The Class is readily identifiable from information and records in Defendants' and other generic drug manufacturers' possession and in the possession of Forest.

68. Plaintiff's claims are typical of members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, Defendants' anticompetitive conduct deprived the Class members of the benefits of competition from less-

expensive generic versions of Bystolic, causing them to pay artificially inflated, supracompetitive prices for brand and generic Bystolic.

69. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

70. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and particularly class action antitrust litigation in the pharmaceutical industry.

71. Questions of law and fact common to members of the Class predominate over questions, if any, that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

72. Questions of law and fact common to the Class include:

a. whether the conduct alleged herein constitutes a violation of the antitrust laws;

b. whether Defendants conspired with Forest to suppress generic competition to Bystolic;

c. whether Defendants' challenged conduct suppressed generic competition to Bystolic;

d. Whether Defendants' challenged conduct fixed, raised, maintained or stabilized the price of nebivolol HCl;

e. whether a relevant antitrust market needs to be defined in this case in light of the existence of direct proof of Forest's power to exclude generic competition and charge supracompetitive prices for Bystolic;

f. if a relevant antitrust market needs to be defined, what the definition of the relevant antitrust market for analyzing Forest's monopoly power is, and whether Forest had monopoly power in the relevant antitrust market;

g. whether Forest illegally obtained or maintained monopoly power in the relevant market;

h. whether Defendants' actions were, on balance, unreasonable restraints of trade;

i. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

j. whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiff and the Direct Purchaser Class; and

k. the quantum of overcharge damages paid by the Class in the aggregate.

73. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that could not be practicably pursued individually, substantially outweigh potential difficulties in management of this class action.

74. Class action treatment is also appropriate under Rule 23(b)(2) because Defendants acted and refused to act on grounds generally applicable to the class, making appropriate final injunctive relief with respect to the class as a whole.

75. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval and Substitution of Generic Drugs

76. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

77. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the

"Orange Book") any patents that both claim the drug or its approved use and could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within thirty days of issuance any patents issued after the FDA approved the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

78. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

i. The Hatch-Waxman Amendments

79. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

80. The FDCA and Hatch-Waxman Amendments operate on the proven scientific principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the

proposed generic drug would be present in the blood of a patient to the same relative extent and for the same amount of time as the brand counterpart. 21 U.S.C. § 355(j)(8)(B).

81. Congress enacted the Hatch-Waxman Amendments to expedite the entry of less-expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

82. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions.[25] Generics are now dispensed 95% of the time when a generic form is available.[26]

ii. ANDA Paragraph IV Certification

83. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

[25] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014), *available at* http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf (last accessed June 6, 2014).

[26] *Id.* at 51.

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

84. If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for alleged patent infringement. Ordinarily, if the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months from the date of receipt of the Paragraph IV notice, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). However, the Hatch-Waxman Act provides for a five-year marketing exclusivity period for a brand-name drug such as Bystolic with an active ingredient that qualifies as a new chemical entity (NCE). During this five-year period, ANDAs cannot be filed. That period is reduced to four years if the ANDA application includes a Paragraph IV Certification. 21 U.S.C. § 355(j)(5)(F)(ii). In the event that a Paragraph IV ANDA is filed at the end of the four-year period and a lawsuit is commenced within forty-five days of the receipt of the Paragraph IV notice, the Hatch-Waxman Act requires that the 30-month stay be "extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval" of the NDA. Until a court decides the patent is invalid or not infringed, or until 7.5 years have elapsed, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (*i.e.*, grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the stay.

iii. First-Filer's 180 Day Exclusivity Period

85. Generics may be classified as (i) first-filer generics, (ii) later generic filers, and (iii) the brand's own authorized generic.

86. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification a 180 day period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand product are either invalid, unenforceable, or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first-filing generic has been on the market for 180 days, or until the first-filer exclusivity has been extinguished or forfeited.

87. The Supreme Court has recognized that "this 180 day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first filer.[27]

88. A first-filer that informs FDA that it intends to wait until all Orange Book listed patents expire before marketing its product does not get a 180 day exclusivity period. Congress created this 180 day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

89. Where (as here) multiple generic companies are the first to file substantially complete ANDAs with Paragraph IV certifications, each is considered a "first applicant" and may be eligible to share the 180 day period.[28] If at least one first applicant remains eligible for the exclusivity, *i.e.*, the exclusivity has not been extinguished or forfeited, all subsequent ANDA filers must wait until the 180 day period expires before they can launch.

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[27] *FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013).

[28] 21 U.S.C. § 355(j)(5)(B)(iv).

B. The Competitive Effects of AB-Rated Generic Competition

90. Since the FDA deems AB-rated generic versions of brand drugs to be just as safe and effective as their brand counterparts, the only material mode of differentiating the two is their price. On average, generics are at least 50% - 80% less expensive when there are multiple generic competitors on the market for a given brand.

91. Every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has affirmatively requested the brand). Accordingly, once one generic equivalent enters the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months.

92. By 12 months post-generic entry, the Federal Trade Commission ("FTC") found that on average, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85% relative to brand prices.[29] That is because, once multiple generic competitors enter, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other for sales by driving prices further down toward marginal manufacturing costs.[30] As a result, competition from generic drugs is viewed by brand drug companies, such as Forest, as a grave financial threat.

93. Generic competition enables purchasers (like Class members here) to purchase substantially cheaper generic versions of a drug instead of the more expensive brand, and to purchase generic versions of a drug at increasingly lower prices as generic prices fall over time

[29] *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010) ("FTC Pay-for-Delay Study"), http://www.ftc.gov/sites/default/files/documents/reports/ pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[30] *See*, *e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311, 314, 339-41, 354-55 (Oct. 2000); Tracy Regan, *Generic Entry and Price Competition in the Prescription Drug Market--18 Years after the Waxman-Hatch Act* 24-25 (Univ. of Miami, Dep't of Econ., Working Paper, Feb. 14, 2004); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1993-96 (Nov. 2007).

and as more generic versions of that brand drug enter the market, causing generic prices to fall further.[31] In addition, generic competition enables purchasers to pay lower prices for their remaining brand purchases when the brand company lowers its brand price to compete with the generic for sales.

94. Conduct that delays generic entry harms direct purchasers (like Plaintiff and Class members here) in several ways. One way that direct purchasers are harmed (suffer overcharges) is that they are forced to continue purchasing the more expensive brand drug instead of the lower-priced generic equivalent they would have purchased had the generics entered earlier. In addition, conduct that delays generic entry causes direct purchasers to pay inflated generic prices because (a) generic prices fall over time, and so generic prices would have been lower if generic competition had started earlier and (b) brand prices typically increase over time[32] and the generic price is discounted off of the brand price,[33] and so the generic prices would have been lower if

[31] *See, e.g.*, Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation* 19-20 (Nat'l Bureau of Econ. Research, Working Paper No. 16431, Oct. 2010); CONGRESSIONAL BUDGET OFFICE, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at 32-33 (Jul. 1997); David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. OF ECON. AND STAT., 37, 43-44 (2005).

[32] The price of brand Bystolic has increased substantially over the last five years. For example, Forest increased the price of the 10 mg tablet of Bystolic repeatedly and significantly over the last five years, by 8.5% in October 2015, 9% in April 2016, 9% in January 2017, 9.5% in January 2018, 9.5% in January 2019, and 5% in January 2020 – in total increasing the price of the 10 mg tablet of Bystolic by 62% over the last five years. Forest took nearly identical price increases on the other strengths of Bystolic, increasing the prices of the various strengths of Bystolic by 60-62% over the period from June 2015 through today.

[33] In order to be automatically substituted for the corresponding brand, generic products must be less expensive than the corresponding brand. *E.g.*, Cal. Bus. & Prof. Code § 4073(c); Tx. Admin. Code § 309.3(a)(1); Fla. Stat. § 465.025(2); 35 Pa. Code § 960.3(a); N.Y. Educ. Law § 6816-a. Generic prices are set as a percentage discount off the brand price. *See, e.g.*, *In re Namenda Antitrust Litig.*, 1:15-cv-07488-CM-RWL (S.D.N.Y. Mar. 5, 2019), (ECF No. 668-4) (assumption listed in cell A43 of a pharmaceutical manufacturer sales forecast is that the generic will initially be priced at a 40 percent discount off the brand price and then will drop to a 90% discount from the brand price).

the generics had launched earlier, when the brand price was lower (since the generic price would have been discounted off a lower brand price).

95. Once exclusivity is lost and generic entry occurs – an event sometimes referred to as the "patent cliff" – the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws. "According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics."[34]

C. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

96. Because the Hatch-Waxman regulatory scheme automatically delays approval of an ANDA whenever a brand name manufacturer sues the potential generic competitor for alleged patent infringement, brand name manufacturers frequently take aggressive positions in listing patents in the Orange Book, and then bring patent lawsuits against any generic competitor that files an ANDA with a Paragraph IV certification. Brand name manufacturers often sue generics simply to delay generic competition, rather than to enforce valid patents against infringing products.

97. In connection with the resolution of patent litigation arising out of Paragraph IV Certifications, some brand name manufacturers have entered into "settlements" in which the brand name manufacturer pays off its generic competitors in exchange for the generics' dropping their patent challenges and delaying generic competition. These exclusion payment agreements among horizontal competitors not to compete are commonly known as "pay-for-delay" or

[34] *Generic Drugs Undergo Rigorous FDA Scrutiny*, U.S. Food & Drug Admin. (Oct. 8, 2014), https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny.

"reverse-payment agreements." Brand and generic manufacturers execute exclusion payment agreements as (or in connection with) purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers. The brand name manufacturer preserves increased profits by keeping its monopoly intact via a payment of some of the monopoly profits to the generic manufacturer, which in turn agrees to drop its patent challenge and delay marketing its product.

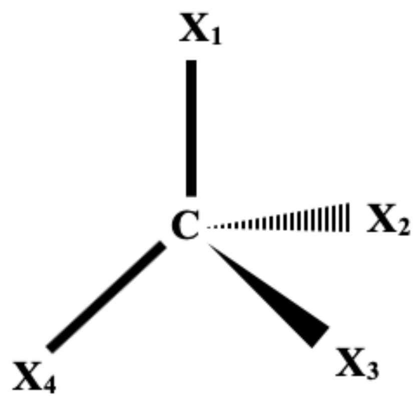
98. Initially reverse-payment agreements took the form of a straight cash payment from the brand name manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and class action lawsuits, brand name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. For example, the reverse-payment deals that were the subject of *FTC v. Actavis*, *Inc.*, 570 U.S. 136 (2013) involved payments allegedly hidden in co-promotion and manufacturing side-deals entered into in connection with settlement of patent litigation over the brand drug AndroGel. Because the profits to be gained by delaying generic competition are so great, however, drug manufacturers retain the incentive to enter into such agreements.

VI. FACTUAL ALLEGATIONS

A. Basic Chemistry Relating to the Active Pharmaceutical Ingredient in the Drug Product Bystolic

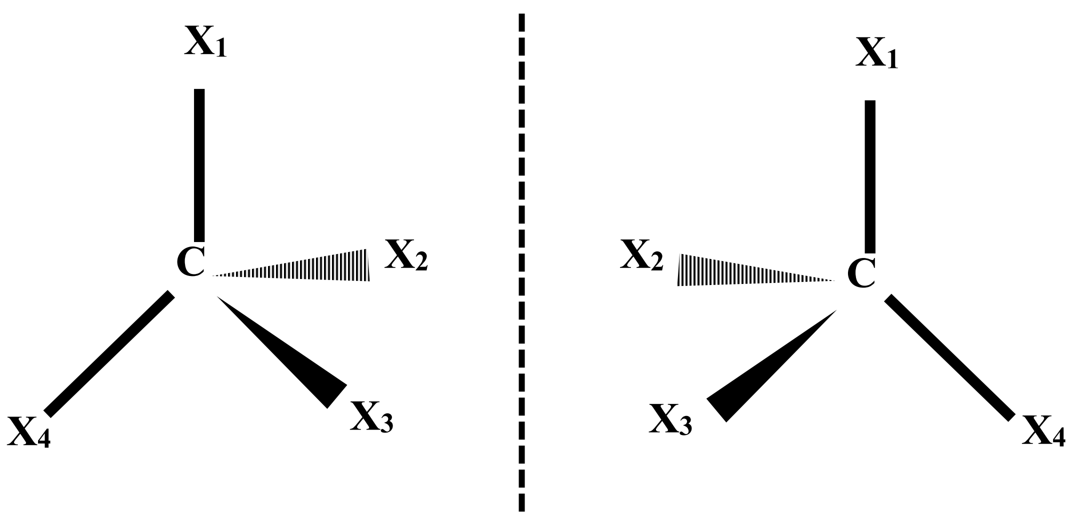
99. Molecules are composed of atoms (*e.g.*, carbon, nitrogen or hydrogen) that are bonded to each other through the sharing of electrons. The atom carbon forms four bonds and tends to adopt a tetrahedral structure. That three-dimensional arrangement can be envisioned as a tetrahedron with the carbon atom at the center and the four substituents at the four vertices of the tetrahedron.

100. The chemical symbol for a carbon atom is "C." The figure below depicts a carbon atom (labeled as "C") bonded to four different chemical substituents (labeled as "X_1," "X_2," "X_3," and "X_4"). The straight lines from the carbon atom (at the center) to "X_1" and "X_4" are



intended to convey that they are in the plane of the page. The solid wedge from the carbon atom to "X_3" is intended to convey that it is coming out of the page towards the reader. And the hashed wedge from the carbon atom to "X_2" is intended to convey that it is coming out of the page but away from the reader. Thus, the above figure reflects a three-dimensional tetrahedral structure with a carbon atom at its center.

101. When a carbon atom is attached to four different substituents in a tetrahedral



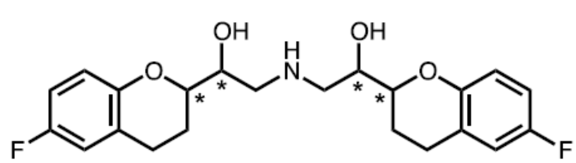
arrangement such as that shown above, the substituents can be arranged in either of two conformations, as depicted above, with a mirror line between them. Note that, much like one's left and right hands, these two arrangements are mirror images of one another. And, much like

one's left and right hands, they cannot be superimposed on one another by rotation. A carbon atom bonded to four different substituents can thus exist as either of two "stereoisomers" and such a carbon atom is referred to as a "chiral center." Naming conventions exist to distinguish these two stereoisomers from one another, and a commonly used terminology refers to one configuration as the "R" configuration and the other as the "S" configuration.

102. Distinguishing between stereoisomers can be particularly important in biological systems because many active pharmaceutical ingredients ("APIs") in drugs interact with naturally occurring receptors in the human body by fitting into a three-dimensional site on the receptor, much like a left hand fits into a left-handed glove. Just as a left hand would not fit properly into a right-handed glove, the wrong stereoisomer often will not fit into the intended receptor site. Thus, it is not uncommon for one stereoisomer to exhibit a desired pharmacological activity in biological systems while the other does not.

103. Carbon is so ubiquitous in organic chemicals that a carbon atom in chemical structures is often abbreviated as a vertex, rather than as a "C," with the understanding that such vertices are carbon. The chemical symbol for hydrogen is "H" and hydrogen only forms one bond. Because hydrogen is also ubiquitous and the number of chemical bonds that carbon and hydrogen make (*i.e.*, 4 and 1, respectively) is so well known, hydrogen is often omitted from chemical structures and its presence is assumed when a carbon has less than four bonded substituents.

104. On March 31, 1987, the United States Patent and Trademark Office ("PTO") issued United States Patent No. 4,654,362 ("the '362 Patent"). The '362 Patent disclosed a number of different chemical compounds, including the following chemical compound:



105. The unlabeled vertices above correspond to a carbon atom and each of those carbon atoms (vertices) is connected to other atoms. To the extent a particular carbon atom has less than four bonds depicted, the remainder are hydrogen atoms. With this understanding in mind, each asterisk in the above chemical structure corresponds to a chiral center – *i.e.*, a carbon atom bonded to four different substituents – that can adopt either of two configurations that can be labeled as either an "R" or "S" configuration. As a result, the above chemical structure discloses ten different possible stereoisomers with the following configurations:

1. SRRR	6. SRSS
2. RSSS	7. RSRR
3. SRRS	8. RRSS
4. RSSR	9. SSSS
5. SRSR	10. RRRR

106. Forest was, and its successor in interest Allergan is, the holder of NDA No. 21-742 for Bystolic. The active ingredient in Bystolic is a mixture of two of the above ten stereoisomers: the SRRR and RSSS stereoisomers (*i.e.*, nos. 1 and 2, above). The mixture of these two stereoisomers is referred to as nebivolol, and both are present in Bystolic as a hydrochloride salt.

B. Forest's Bystolic Patents

107. Forest certified to FDA that the '040 and '580 Patents covered Bystolic, and FDA listed those patents in the Orange Book. The '580 Patent issued on June 2, 1998 and expired seventeen years later, on June 2, 2015. Accordingly, the '580 Patent afforded Forest no protection from generic competition for Bystolic beyond June 2, 2015. Further, some or all of the Defendants filed Paragraph IV certifications as to the '580 Patent and Forest declined to sue any of the Defendants on that patent.

108. The ’040 Patent issued from United States Application Serial No. 07/825,488 (“the ’488 Application”) filed on January 24, 1992. The ’040 Patent issued on April 8, 2003 and is set to expire on December 17, 2021. To understand the impact of prosecution of the ’488 Application at the PTO on the scope of the issued claims in the ’040 Patent, it is important to understand the effect of the choice of transition in a patent claim. “A patent claim typically has three parts: the preamble, the transition, and the body.” Donald S. Chisum, CHISUM ON PATENTS § 8.06[1](b) (2003). “The preamble is an introductory phrase that may summarize the invention, its relation to the prior art, or its intended use or properties.” *Id.* § 8.06[1](b)[i]. “The transition is a phrase connecting the preamble to the body of the claim. The content of the phrase may indicate whether the elements stated in the body are ‘open’ or ‘closed.’” *Id.* § 8.06[1](b)[ii]. “The body of the claim is the recitation or listing of the elements and limitations which define the product or process to be encompassed within the patent monopoly.” *Id.* § 8.06[1](b)[iii].

109. There are three commonly used transitional phrases: “comprising,” “consisting of,” and “consisting essentially of.” *Id.* § 8.06[1](b)[ii]; *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006). These are “terms of art in patent law that ‘define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.’” *Id.* (quoting the Manual of Patent Examining Procedures). At one end of the spectrum, the phrase “comprising” signifies that the claim is “open” to the addition of unrecited components or steps. *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). For example, a claim reciting a product “comprising” three ingredients A, B and C encompasses a product composed of A, B, C and D (*i.e.*, the addition of D to the A-B-C combination does not avoid infringement).

110. The originally-filed claims in the application that issued as the ’040 Patent employed the open transition “comprising.” For example, originally-filed claim 19 covered pharmaceutical compositions “comprising” a “pharmaceutically acceptable carrier” and the SRRR and RSSS stereoisomers of nebivolol. The use of the open transition “comprising” meant that original claim 19 covered formulations having the SRRR and RSSS stereoisomers of

nebivolol, even if the formulations also included some or all of the other eight unclaimed stereoisomers of nebivolol. The PTO examiner therefore rejected those claims based upon the prior art '362 Patent described above. The examiner reasoned that the '362 Patent taught mixtures of various of the stereoisomers described above, and thus were covered by pending claim 19.

111. In response, the applicants admitted that the '362 Patent taught "undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of the Base Compound. . . ." More specifically, the applicants admitted that "Compound 84 . . . is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 . . . is an undefined mixture of the RSRS, RSSR, and SRRS isomers." In an attempt to overcome the rejection, the applicants narrowed the claims by substituting new claims utilizing the transition "consisting essentially of" rather than "comprising." In doing so, the applicants emphasized that the purpose of the amendment was to distinguish their claims from the undefined mixtures of other nebivolol isomers disclosed in the Prior Art '362 Patent:

> Claims 18 and 19 have been rewritten as new Claims 25 and 26. Claim 25 recites "A composition consisting essentially of the compound . . .", and Claim 26 recites "A pharmaceutical composition consisting essentially of . . . [the two compounds (a) and (b)]". This amendment is being made to more clearly distinguish the claimed invention over the prior art ['362 Patent] which, as is explained in detail below, discloses undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of [nebivolol]. Favorable consideration of the amended claims is respectfully requested.

112. The transition "consisting essentially of" in a patent claim narrows the claim relative to "comprising." *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). "[W]ith respect to a 'consisting essentially of' claim, there is no infringement where the accused product contains additional, unclaimed ingredients that materially affect the basic and novel properties of the invention." *Yoon Ja Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1320-21 (Fed. Cir. 2006). Thus, for a claim reciting a product "consisting essentially of" ingredients A, B and C, the addition of unrecited ingredient D will avoid infringement if D has a material effect on the basic and novel properties of the claimed invention.

113. The PTO examiner, however, was not persuaded that the use of the "consisting essentially of" transition distinguished the then-pending claims from the '362 Patent. He therefore maintained his rejection of the claims. The applicants for the '040 Patent again argued that it was impossible to tell from the '362 Patent which stereoisomers, and in what amounts, were definitely present in the disclosed mixtures:

> There is no way that one can determine from the teachings of the patent the specific stereoisomeric configuration of [the prior art '362 Patent's] compound Nos. 84 and 87.

The Examiner continued to maintain his rejections and ultimately issued a final rejection of the "consisting essentially of" Claims 25 and 26, as anticipated by the '362 Patent. He also rejected the claims as obvious.

114. The applicants for the '040 Patent appealed the examiner's final anticipation and obviousness rejections to the Board of Patent Appeals and Interferences ("the Board"). In their brief, the applicants continued to argue that it was impossible to say exactly which stereoisomers (and how much of them) were present in Compound 84 of the prior art '362 Patent, but that the "possible" stereoisomers present in unknown amounts were RSRR, RSSS, SRRR and SRSS. During the course of briefing the appeal to the Board, the Examiner dropped the anticipation rejection.

115. The Board nevertheless addressed the anticipation issue and made certain findings and conclusions regarding the relationship between then-pending Claim 26 and Compound 84 of the '362 Patent. Specifically, the Board concluded:

> [The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers "just as surely as if they were identified in the reference by name."

116. The Board then determined that the "consisting essentially of" transition in then-pending Claim 26 caused the claim to cover the undefined mixture of isomers in the Prior Art '362 Patent:

> It is well settled that "the phrase 'consisting essentially of' limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristic(s) of a composition." Here, a basic and novel

> characteristic of the pharmaceutical composition of claim 26 is its blood pressure reducing or antihypertensive effect. Thus, claim 26 is open to ingredients that do not materially affect its antihypertensive activity. [The prior art '362 Patent's] antihypertensive compound 84 is a mixture of four stereoisomers: RSSS, SRRR, RSRR and SRSS. ***Because the RSSR and SRSS stereoisomers do not materially affect blood pressure reducing or antihypertensive activity, it appears that they are not excluded from the composition of claim 26***.

(internal citation omitted and emphasis added). Accordingly, the Board ordered the Examiner to reconsider his withdrawal of the anticipation rejection based on the Prior Art '362 Patent:

> Specifically, the examiner should consider whether claim 26 'reads on' [the '362 Patent's] compound 84 taking into account the appropriate principles of claim interpretation and the foregoing remarks.

The very clear upshot of the Board's decision was that the claims of the '488 Application were not patentable unless the claims excluded the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers.

117. On remand from the Board, the applicants for the '040 Patent did not even attempt to argue against anticipation in view of the Board's opinion. Instead, they further narrowed their claims by replacing "consisting essentially of" with "consisting of," in new Claims 27 and 28. And based on that change, applicants argued that the new "consisting of" limitation excluded the undefined mixture of possible stereoisomers in the '362 Patent:

> Applicants respectfully submit that the claims, as amended, are patentable over [the prior art '362 Patent]. Applicants submit that neither a composition consisting of the RSSS enantiomer, nor a composition consisting of the RSSS enantiomer and its enantiomer the SRRR enantiomer, are disclosed in [the '362 Patent]. [The '362 Patent] discloses the base compound, as an undefined mixture of stereoisomers, as compound 84 (designated as "AB") and 87 (designated as "AA"), shown in the table in Col. 21 of the patent.

118. Once again, the applicants expressly noted that "Compound 84 [of the prior art '362 Patent] is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 [] is an undefined mixture of the RSRS, RSSR, and SRRS isomers." They argued that the new "consisting of" language excluded compounds containing such additional isomers:

> [I]t is clear that the cited [the '362 Patent] discloses neither a composition consisting of the RSSS enantiomer of the base compound, nor a composition consisting of the RSSS and SRRR enantiomers.

119. And again, applicants did not distinguish their claims based on any particular amount or source of possible unrecited stereoisomers in the "undefined mixture" of the '362 Patent.

120. The phrase "consisting of" is the narrowest of the transitions and it "signifies restriction and exclusion of unrecited steps or components." Manual of Patent Examining Procedures § 2111.03; *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004). In light of the Board's reasoning and the applicants' comments and amendments, it is clear that the narrowing amendment was intended to and did exclude the presence of the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers (*i.e.*, the claims do not cover formulations containing the unclaimed stereoisomers, especially the RSSR and SRSS stereoisomers).

121. The Examiner then allowed the "consisting of" Claims 27 and 28, which ultimately issued as Claims 2 and 3 of the '040 Patent in 2003.

122. Subsequently, the '040 Patent was subjected to reexamination proceedings and a reexamination certificate issued in 2009.

C. The Defendants File ANDAs for Generic Versions of Bystolic

123. Alkem, Amerigen, Glenmark, Indchemie, Hetero, Torrent and Watson were the first generic manufacturers to file ANDAs with the FDA containing Paragraph IV certifications regarding the Bystolic patents. For example, in letters granting final approval to their ANDAs, the FDA noted that each was "one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Nebivolol Tablets."[35]

124. Because the Defendants were the first companies to file substantially complete ANDAs with Paragraph IV certifications, each stood to receive 180 days of marketing exclusivity

[35] *See, e.g.*, 11/27/2015 Letter from FDA to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf; 5/27/2017 Letter from FDA to Glenmark, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf; 6/24/2015 Letter from FDA to Alkem, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/ 203741Orig1s000ltr.pdf.

during which the FDA would not give final approval to any later ANDA filer's generic equivalent of Bystolic.

125. Forest received the Defendants' Paragraph IV notice letters on the following dates:

- Torrent: February 2, 2012[36]
- Indchemie: February 3, 2012[37]
- Alkem: February 3, 2012[38]
- Watson: February 13, 2012[39]
- Amerigen: February 16, 2012[40]
- Hetero: February 17, 2012[41]
- Glenmark: February 20, 2012[42]

126. Because they contained Paragraph IV certifications, these notice letters were required to include a detailed statement of the factual and legal bases as to why the '040 Patent (and the '580 Patent, to the extent it was challenged) was invalid, unenforceable, and/or not infringed by their ANDA products. The Paragraph IV notice letters were required to include an offer of confidential access to each Defendant's ANDA under the Hatch-Waxman Act. The notice letters gave rise to a potential cause of action for patent infringement, thereby allowing Forest to file suit against the Defendants under the Hatch-Waxman Act (if Forest otherwise had a basis to sue under Rule 11).

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[36] *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 93).

[37] *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1 ¶ 22).

[38] *Id.* ¶ 38.

[39] *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 108).

[40] *Id.* ¶ 123.

[41] *Id.* ¶ 153.

[42] *Id.* ¶ 138.

D. The Nebivolol Patent Litigation

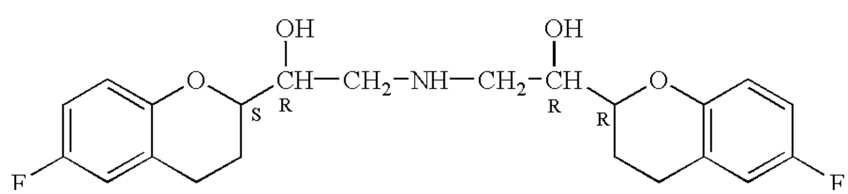
127. On March 13, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Torrent, Watson, Amerigen, Glenmark, and Hetero.[43] Despite having received Paragraph IV Certification notice letters from some or all of these companies relating to both the ’040 and ’580 Patents, Forest chose to assert only the ’040 Patent.

128. On March 14, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the Northern District of Illinois against Indchemie and Alkem.[44] Despite having received Paragraph IV Certification notice letters from both Indchemie and Alkem relating to both the ’040 and ’580 Patents, Forest chose to assert only the ’040 Patent.

129. By order of the Judicial Panel for Multidistrict Litigation, these seven patent cases were consolidated into *In re Nebivolol Patent (’040) Litigation*, 12-cv-5026 (N.D. Ill. June 12, 2012) (ECF No. 1) (hereafter referred to as the “Nebivolol Patent Litigation”).

130. Forest could not prevail in the Nebivolol Patent Litigation. The sole independent claim asserted by Forest in the Nebivolol Patent Litigation was claim 2 of the ’040 Patent, as shown below:

> 2. A pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients:
>
> (a) the blood pressure reducing compound [2S,αR, 2′R,α′R]-α,α′-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:

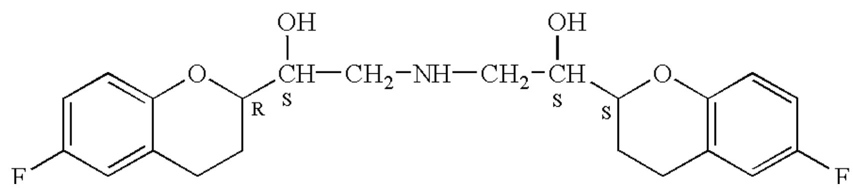


[43] *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1).

[44] *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1).

or a pharmaceutically acceptable acid addition salt thereof; and

(b) the compound [2R,αS,2′S,α′S]-α,α′-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



or a pharmaceutically acceptable acid addition salt thereof.

’040 Patent at 11:33-12:22. Thus, claim 2 is limited to a pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients, SRRR-nebivolol and RSSS-nebivolol (or pharmaceutically acceptable acid addition salts).

131. The Defendants were well aware of the prosecution history of the ’040 Patent and the narrowing amendments the applicants had made. During claim construction proceedings in the Nebivolol Patent Litigation, they correctly argued that the term “consisting of” in claim 2 of the ’040 Patent “excludes any unrecited stereoisomers of nebivolol.” The Defendants’ generic Bystolic products did not infringe because they included at least small amounts of the unrecited stereoisomers of nebivolol, including the RSSR and SRSS stereoisomers.

132. Early on in the Nebivolol Patent Litigation, the Defendants pressed the argument that the “consisting of” transition precluded the use of a plurality of inactive ingredients. Their position was premised on the argument that (1) a “pharmaceutically acceptable carrier” referred to an individual inactive ingredient in a pharmaceutical formulation; (2) the “consisting of” transition “closed” the claim to unrecited inactive ingredients; and (3) therefore, the claims did not cover formulations having two or more inactive ingredients. At least one other court has construed “pharmaceutically acceptable carrier” to mean “a conventional pharmaceutically acceptable excipient or additive. . . .” *Schering Corp. v. Mylan Pharms., Inc.*, 2011 U.S. Dist. LEXIS 63825, at *36 (D.N.J. Jun. 15, 2011). To the extent this interpretation applied in the Nebivolol Patent Litigation, the Defendants’ products did not infringe for this additional reason.

133. As a result of the foregoing, Forest could not prevail in proving literal infringement of the asserted claims of the ’040 Patent. And, in light of the prosecution history of the ’040 Patent, Forest could not prevail based on the doctrine of equivalents. In addition, Forest’s invalidity defenses concerning the asserted claims of the ’040 Patent were weak and it could not have prevailed against the Defendants’ invalidity arguments. As the Board explained during the prosecution of the ’040 Patent:

> [The ’362 Patent’s] disclosure of compound 84, together with its designation “AB,” appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers “just as surely as if they were identified in the reference by name.”

The ’362 Patent was prior art to the ’040 Patent. In light of the ’362 Patent’s essentially explicit teaching of a mixture of “the individual RSSS, SRRR, RSRR and SRSS stereoisomers” of nebivolol, the asserted compositions in the ’040 Patent were anticipated by, or obvious in view of, the prior art, including other pertinent prior art such as Van de Water et al., Pharmacological and Hemodynamic Profile of Nebivolol, a Chemically Novel, Potent, and Selective B1-Adrenergic Antagonist, Journal of Cardiovascular Pharmacology, 11, No. 5, 552-563 (1988). Any purported evidence of secondary indicia of nonobviousness was insufficient to overcome the clear *prima facie* obviousness of the claims.

E. Forest Enters into Unlawful Reverse-Payment Agreements with the Defendants

134. Starting on October 24, 2012, Forest began entering into settlements with the Defendants to resolve the Nebivolol Patent Litigation. Forest’s internal and external counsel have conceded that each of these settlements also included “side-deals”:


To: 'Malester, Ann'[]; Newborn, Steven[steven.newborn@weil.com]
From: Agovino, Eric

Sent: Tue 3/4/2014 7:47:28 PM
Importance: Normal
Subject: RE: Namenda settlements
Received: Tue 3/4/2014 7:47:00 PM
EXECUTED Forest-Hetero Settlement and License Agreement.pdf
EXECUTED Term Sheet (Hetero).pdf

We entered into settlement agreements with the following defendants:

1) Hetero

2) Torrent

3) Alkem

4) Indchemie

5) Glenmark

6) Amerigen

7) Actavis

All had side deals (one side was struck with Alkem, which is a related company with Indchemie).

Attached are the Hetero agreements.

From: Malester, Ann [mailto:Ann.Malester@weil.com]
Sent: Tuesday, March 04, 2014 9:15 AM
To: Agovino, Eric; Newborn, Steven
Subject: RE: Namenda settlements

Eric,

Before we engage in any discussions with the FTC on the Namenda agreements, we think it would be prudent for us to review all of the Bystolic settlement and licensing agreements as well as the side agreements with those generic companies. Could you put together the same type of information for Bystolic as you sent us for Namenda?

Thanks so much, Ann

135. These side-deals were also listed in Forest's Merger Agreement with Actavis PLC as "material contracts" that on information and belief "involve payments . . . of consideration in excess of $15,000,000."[45] In addition, Forest has also admitted that it reimbursed "certain of the Settling Defendants' legal costs in connection with the patent litigation."[46] Accordingly, on information and belief, Forest paid each Defendant at least $15,000,000 but likely more, in reverse payments to resolve the Nebivolol Patent Litigation and induce the Defendants to quit the patent fight. Each Defendant readily accepted these payments to do so.

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[45] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

[46] https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm.

136. The **Hetero** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012," plus payment for Hetero's expended litigation costs, and a "FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute."[47]

137. On information and belief, in addition to the monies Forest paid Hetero for Hetero's expended litigation costs, pursuant to the "FINAL TERM SHEET," Forest paid Hetero more than $15,000,000.

138. The **Torrent** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012," plus payment for Torrent's expended litigation costs, and a "PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[48]

139. On information and belief, in addition to the monies Forest paid Torrent for Torrent's expended litigation costs, pursuant to the "PATENT ASSIGNMENT AGREEMENT," Forest paid Torrent more than $15,000,000.

140. The **Alkem** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012," plus payment for Alkem's expended litigation costs, and a "TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with

[47] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 179).

[48] *Id*.

the settlement of BYSTOLIC patent dispute." Alkem and Forest also entered into an "AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT . . . on January 9, 2013."[49]

141. On information and belief, in addition to the monies Forest paid Alkem for Alkem's expended litigation costs, pursuant to the Alkem "TERM SHEET," Forest paid Alkem more than $15,000,000.

142. The **Indchemie** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Indchemie Health Specialties Private Ltd. dated November 27, 2012," plus payment for Indchemie's expended litigation costs, and a "TERM SHEET between Alkem Laboratories Ltd, Indchemie Health Specialties Private Ltd, and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute."[50]

143. On information and belief, in addition to the monies Forest paid Indchemie for Indchemie's expended litigation costs, pursuant to the Indchemie "TERM SHEET," Forest paid Indchemie more than $15,000,000.

144. The **Glenmark** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012," plus payment for Glenmark's expended litigation costs, and a "COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[51]

145. On information and belief, in addition to the monies Forest paid Glenmark for Glenmark's expended litigation costs, pursuant to the "COLLABORATION AND OPTION AGREEMENT," Forest paid Glenmark more than $15,000,000.

[49] *Id*.

[50] *Id*.

[51] *Id*.

146. The **Amerigen** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013," plus payment for Amerigen's expended litigation costs, and a "BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute."[52]

147. On information and belief, in addition to the monies Forest paid Amerigen for Amerigen's expended litigation costs, pursuant to the "BINDING TERM SHEET COLLABORATION AGREEMENT," Forest paid Amerigen more than $15,000,000.

148. The **Watson** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013," plus payment for **Watson** expended litigation costs, and "(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute."[53]

149. On information and belief, in addition to the monies Forest paid Watson for Watson's expended litigation costs, pursuant to the "(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc.," Forest paid Watson more than $15,000,000.

[52] *Id*. at 180.

[53] *Id*.

150. On information and belief, the value of each reverse-payment exceeded Forest's avoided litigation costs.

151. In exchange for these reverse-payments, each Defendant agreed not to compete with Forest in the market for nebivolol HCl, in which Forest had a monopoly, for so long as all others did so also, until September 17, 2021 (a mere three months prior to expiry of the '040 Patent).[54]

152. The purpose and effect of the reverse-payment agreements were to delay Forest from having to face lower-priced generic competition for years.

153. But for the reverse-payment agreements, the Defendants would have been ready, able, and willing to launch their generic versions of Bystolic much earlier.

154. Specifically, the Defendants would have launched their less-expensive generic versions of Bystolic earlier than September 17, 2021: (a) at risk during pendency of the Nebivolol Patent Litigation; (b) upon prevailing against Forest in the Nebivolol Patent Litigation; or (c) via lawful, procompetitive settlement agreements providing for earlier negotiated entry dates untainted by the delay caused by the unlawful reverse payments.

155. By operation of the CLPs, if *just one* Defendant launched a generic version of Bystolic prior to September 17, 2021 pursuant to any of the three above scenarios, *all* of the other Defendants would have entered the market.

156. By about October 2012, when Forest and the Defendants began entering into the reverse-payment agreements, Bystolic was generating hundreds of millions of dollars per year in revenues for Forest. Losing a substantial portion of that revenue stream in the event any of the Defendants were to prevail on non-infringement or other defenses – or in the event that Forest had not induced the Defendants with reverse-payments to agree to delay launching generic Bystolic – would have drastically reduced Forest's profits. Thus, Forest had enormous incentives to avoid competition from the Defendants by entering into reverse-payment agreements. Each

[54] https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm.

Defendant also had incentive to accept a reverse payment because (on information and belief) each reverse payment represented more profit than the Defendant would have made by competing with Forest and with the other Defendants because, *inter alia*, the market entry of multiple generics competing on price quickly lowers generic prices toward marginal costs.

157. Each Defendant's willingness to accept large payments from Forest in exchange for a multi-year delay in competition amounted to an agreement between each Defendant and Forest to share the monopoly profits from sales of branded Bystolic at supracompetitive levels.

VII. ANTICOMPETITIVE EFFECT

158. The reverse payments caused Defendants to: (a) prevent and delay until September 17, 2021 the entry of less-expensive generic versions of Bystolic in the United States; (b) fix, raise, maintain, or stabilize the price of Bystolic; and (c) allocate to Forest 100% of the U.S. market for Bystolic and its generic equivalents until September 17, 2021.

159. But for the unlawful reverse-payment agreements, the Defendants would have begun selling less expensive generic versions of Bystolic much earlier than September 17, 2021. Such sales would have occurred via market entry by any of the Defendants upon a Defendant litigation victory, via an at risk launch during the pendency of the patent litigation, or via a licensed entry in a settlement with Forest that did not include a side-deal or any other unlawful reverse payments from Forest to any Defendant.

160. An increasingly competitive market for Bystolic and its generic equivalents, with lower prices, would have thereafter emerged as additional generic versions of Bystolic (including, on information and belief, an authorized generic version of Bystolic) entered the market. Plaintiff would have purchased generic Bystolic had it been available.

161. Defendants' unlawful concerted action has (a) delayed and suppressed the sale of generic versions of Bystolic in the United States, (b) enabled Forest to sell Bystolic at artificially inflated, supracompetitive prices, and (c) caused Plaintiff and the Class to pay supracompetitive prices for nebivolol HCl tablets.

162. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT

163. During the class period, Plaintiff and members of the Class purchased substantial amounts nebivolol HCl directly from Forest and others at supracompetitive prices. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay and did pay artificially inflated prices for their requirements for nebivolol HCl. Those prices were substantially greater than the prices that Plaintiff and members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of branded Bystolic was artificially inflated by Defendants' illegal conduct, (2) Plaintiff and Class members were deprived of the opportunity to purchase lower-priced generic versions of Bystolic instead of brand Bystolic sooner, which they would have done had they had the opportunity, and/or (3) Plaintiff and Class members would have paid lower prices for generic Bystolic than the prices they will have actually paid for generic Bystolic.

164. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

IX. EFFECT ON INTERSTATE COMMERCE

165. At all material times, Forest manufactured, promoted, distributed, and/or sold substantial amounts of Bystolic in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. As a direct result of the unlawful reverse-payment agreements, the Defendants refrained from selling generic versions of Bystolic in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States when they otherwise would have done so. During the relevant time period, in connection with the purchase and sale of Bystolic, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

166. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants as alleged in this Complaint were within the flow of, and have substantially affected, interstate commerce.

X. MONOPOLY POWER AND MARKET DEFINITION

167. At all relevant times, Forest had monopoly power over nebivolol HCl products because Forest had the power to maintain the price of the drug it sold as Bystolic at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Bystolic.

168. "[T]he 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level."[55] And a firm that lacks monopoly power is not "likely to pay 'large sums' to induce 'others to stay out of its market.'"[56]

169. A small but significant, non-transitory price increase for Bystolic by Forest would not have caused (and did not cause) a significant loss of sales to non-nebivolol HCl products.

170. Bystolic does not exhibit significant, positive cross-elasticity of demand with respect to price with any non-nebivolol HCl product. Indeed, Forest has never lowered the price of Bystolic in response to the pricing of any non-nebivolol HCl treatments for high blood pressure. In fact, Forest substantially increased the price of Bystolic – by more than 60% – over the last five years.

171. Because of its labeling, Bystolic is differentiated from all non-nebivolol HCl products.

172. Forest needed to control only nebivolol HCl, and no other products, in order to maintain the price of Bystolic profitably at supracompetitive prices. No non-nebivolol HCl

[55] *Actavis*, 570 U.S. at 157 (citation omitted).

[56] *Id.*

product ever rendered Forest unable to profitably maintain or raise their prices of Bystolic without losing substantial sales.

173. Forest also sold Bystolic at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

174. Forest has had, and exercised, the power to exclude and restrict competition to nebivolol HCl.

175. Forest, at all relevant times, enjoyed high barriers to entry with respect to competition to the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

176. Plaintiff alleges that the relevant market is nebivolol HCl. During the period relevant to this case, Forest has been able to profitably maintain the price of nebivolol HCl well above competitive levels.

177. The relevant geographic market is the United States and its territories.

178. At all relevant times, Forest's market share in the relevant market was and remains 100%, implying a substantial amount of monopoly power.

XI. CLAIM ONE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN HETERO AND FOREST)

179. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

180. Forest and Hetero have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

181. Starting on or about October 5, 2012, Forest and Hetero entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse-payments to Hetero in exchange for Hetero's agreement to delay bringing its generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-

payment agreements were to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

182. The Hetero reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

183. The Hetero reverse-payment agreements harmed Plaintiff and the Class as set forth above.

184. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payments from Forest to Hetero that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

185. As a direct, proximate, foreseeable, and intended result of the Hetero reverse-payment-agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse payment, Hetero would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Hetero would have agreed upon earlier entry dates untainted by delay associated with the unlawful Hetero side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Hetero and Forest would also have applied to all earlier-settling Defendants, if any.

XII. CLAIM TWO
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN TORRENT AND FOREST)

186. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

187. Forest and Torrent have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

188. Starting on or about November 21, 2012, Forest and Torrent entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse-payments to Hetero in exchange for Torrent's agreement to delay bringing its generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements were to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

189. The Torrent reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

190. The Torrent reverse-payment agreements harmed Plaintiff and the Class as set forth above.

191. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payments from Forest to Torrent that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

192. As a direct, proximate, foreseeable, and intended result of the Torrent reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse payment, Torrent would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Torrent would have agreed upon earlier entry dates untainted by delay associated with the unlawful Torrent side-deal and

other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Torrent and Forest would also have applied to all earlier-settling Defendants.

XIII. CLAIM THREE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN ALKEM, ASCEND AND FOREST)

193. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

194. Forest, Alkem and Ascend have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

195. Starting on or about November 27, 2012, Forest and Alkem entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse-payments to Alkem in exchange for Alkem's agreement to delay bringing generic Bystolic to the market until September 17, 2021.

196. On information and belief Ascend is a United States agent of Alkem for purposes of effectuating the Alkem-Forest conspiracy. Specifically, Ascend is a wholly owned subsidiary of Alkem, is controlled by Alkem, and engages in the sales and marketing of Alkem's drugs, which but for the Ascend-Alkem relationship, Alkem would have to undertake itself. On information and belief, Ascend joined the Alkem-Forest conspiracy by agreeing to facilitate it by marketing and distributing Alkem's delayed generic version of Bystolic starting on September 17, 2021. But for the unlawful reverse payment agreement, Alkem/Ascend would have done so sooner. On information and belief, the price of generic Bystolic will be supracompetitive for a period of time even after generic entry and Ascend will distribute Alkem's generic Bystolic at supracompetitive prices starting on September 17, 2021.

197. The purpose and effect of Alkem and Ascend's conduct were to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic

competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

198. The Alkem reverse-payment agreements, which Ascend facilitated, were unlawful and the reverse-payments were large and unjustified.

199. The Alkem reverse-payment agreements, which Ascend facilitated, harmed Plaintiff and the Class as set forth above.

200. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Alkem that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

201. There is and was no legitimate, non-pretextual, procompetitive justification for Ascend's conduct that outweighs its harmful effect. Even if there were some conceivable such justification, the conduct was not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

202. As a direct, proximate, foreseeable, and intended result of the Alkem reverse-payment-agreements in restraint of trade, which Ascend facilitated, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse payment, Alkem and Ascend would have launched Alkem's generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Alkem would have agreed upon earlier entry dates untainted by delay associated with the unlawful Alkem side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Alkem and Forest would also have applied to all earlier-settling Defendants.

XIV. CLAIM FOUR
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN INDCHEMIE AND FOREST)

203. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

204. Forest and Indchemie have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

205. Starting on or about November 27, 2012, Forest and Indchemie entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse payments to Indchemie in exchange for Indchemie's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements were to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

206. The Indchemie reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

207. The Indchemie reverse-payment agreements harmed Plaintiff and the Class as set forth above.

208. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Indchemie that outweighs its harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

209. As a direct, proximate, foreseeable, and intended result of the Indchemie reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse payment, Indchemie would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent

settlement agreement whereby reasonable parties in the position of Forest and Indchemie would have agreed upon earlier entry dates untainted by delay associated with the unlawful Indchemie side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Indchemie and Forest would also have applied to all earlier-settling Defendants.

XV. CLAIM FIVE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN GLENMARK AND FOREST)

210. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

211. Forest and Glenmark have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

212. Starting on or about December 21, 2012, Forest and Glenmark entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse payments to Glenmark in exchange for Glenmark's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements were to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

213. The Glenmark reverse-payment agreements were unlawful and the reverse payments were large and unjustified.

214. The Glenmark reverse-payment agreements harmed Plaintiff and the Class as set forth above.

215. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Glenmark that outweighs its harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

216. As a direct, proximate, foreseeable, and intended result of the Glenmark reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse payment, Glenmark would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Glenmark would have agreed upon earlier entry dates untainted by delay associated with the unlawful Glenmark side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Glenmark and Forest would also have applied to all earlier-settling Defendants.

XVI. CLAIM SIX
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN AMERIGEN AND FOREST)

217. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

218. Forest and Amerigen have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

219. Starting on or about July 18, 2012, Forest and Amerigen entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse payments to Amerigen in exchange for Amerigen's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements were to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until

September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

220. The Amerigen reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

221. The Amerigen reverse-payment agreements harmed Plaintiff and the Class as set forth above.

222. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Amerigen that outweighs its harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

223. As a direct, proximate, foreseeable, and intended result of the Amerigen reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse payment, Amerigen would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Amerigen would have agreed upon earlier entry dates untainted by delay associated with the unlawful Amerigen side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Amerigen and Forest would also have applied to all earlier-settling Defendants.

XVII. CLAIM SEVEN
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN WATSON AND FOREST)

224. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

225. Forest and Watson have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

226. Starting on or about November 1, 2013, Forest and Watson entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse payments to Watson in exchange for Watson's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements were to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

227. The Watson reverse-payment agreements were unlawful and the reverse payments were large and unjustified.

228. The Watson reverse-payment agreements harmed Plaintiff and the Class as set forth above.

229. By operation of the CLPs in the other Generic Competitors' reverse-payment agreements, Watson, in negotiating an entry date with Forest, could have accelerated the launch date of generic Bystolic by insisting on an entry date earlier than September 17, 2021 untainted by a reverse-payment side-deal. Instead, Watson chose to bargain for a side-deal with the same launch date as every other Generic Competitor. Thus, the Watson reverse-payment agreements are individually responsible for all of the delay in market entry of generic versions of Bystolic, and are individually responsible for all of Plaintiff's damages.

230. The Watson reverse-payment agreements were unlawful and were large and unjustified.

231. The Watson reverse-payment agreements harmed Plaintiff and the Class as set forth above.

232. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Watson that outweighs its harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

233. As a direct, proximate, foreseeable, and intended result of the Watson reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse payment, Watson would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Watson would have agreed upon earlier entry dates untainted by delay associated with the unlawful Watson side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Watson and Forest would also have applied to all earlier-settling Defendants.

XVIII. CLAIM EIGHT
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN HETERO AND FOREST)

234. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

235. At all relevant times prior to September 17, 2021, Forest possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Forest possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

236. Through the Hetero reverse-payment agreements, Forest and Hetero conspired to unlawfully maintain Forest's monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

237. The Hetero reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions

of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

238. The goal, purpose and/or effect of the Hetero reverse-payment agreements was to maintain, enhance, and extend Forest's monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Hetero reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

239. Forest and Hetero knowingly and intentionally conspired to maintain, enhance, and extend Forest's monopoly power in the relevant market.

240. Forest and Hetero specifically intended that the reverse-payment agreements would maintain Forest's monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

241. Forest and Hetero each committed at least one overt act in furtherance of the conspiracy.

242. As a direct, proximate, foreseeable, and intended result of Forest's and Hetero's concerted monopolistic conduct, as alleged herein, Forest unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse-payment, Hetero would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Hetero would have agreed upon earlier entry dates untainted by delay associated with the unlawful Hetero side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Hetero and Forest would also have applied to all earlier-settling Defendants, if any.

XIX. CLAIM NINE
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN TORRENT AND FOREST)

243. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

244. At all relevant times prior to September 17, 2021, Forest possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Forest possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

245. Through the Torrent reverse-payment agreements, Forest and Torrent conspired to unlawfully maintain Forest's monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

246. The Torrent reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

247. The goal, purpose and/or effect of the Torrent reverse-payment agreements was to maintain, enhance, and extend Forest's monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Torrent reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Forest to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

248. Forest and Torrent knowingly and intentionally conspired to maintain, enhance, and extend Forest's monopoly power in the relevant market.

249. Forest and Torrent specifically intended that the reverse-payment agreements would maintain Forest's monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

250. Forest and Torrent each committed at least one overt act in furtherance of the conspiracy.

251. As a direct, proximate, foreseeable, and intended result of Forest's and Torrent's concerted monopolistic conduct, as alleged herein, Forest unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Torrent would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Torrent would have agreed upon earlier entry dates untainted by delay associated with the unlawful Torrent side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Torrent and Forest would also have applied to all earlier-settling Defendants.

XX. CLAIM TEN
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN ALKEM, ASCEND AND FOREST)

252. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

253. At all relevant times prior to September 17, 2021, Forest possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Forest possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

254. Through the Alkem reverse-payment agreements, Forest and Alkem conspired to unlawfully maintain Forest's monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic. On information and belief Ascend is a United States agent of Alkem for purposes of effectuating the Alkem-Forest conspiracy. Specifically, Ascend is a wholly owned subsidiary of Alkem, is controlled by Alkem, and engages in the sales and marketing of Alkem's drugs, which but for the Ascend-Alkem relationship, Alkem would

have to undertake itself. On information and belief, Ascend joined the Alkem-Forest conspiracy by agreeing to facilitate it by marketing and distributing Alkem's delayed generic version of Bystolic starting on September 17, 2021. But for the unlawful reverse payment agreement, Alkem/Ascend would have done so sooner. On information and belief, the price of generic Bystolic will be supracompetitive for a period of time even after generic entry and Ascend will distribute Alkem's generic Bystolic at supracompetitive prices starting on September 17, 2021.

255. The Alkem reverse-payment agreements, which Ascend willfully facilitated, (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

256. The goal, purpose and/or effect of the Alkem reverse-payment agreements, which Ascend willfully facilitated, was to maintain, enhance, and extend Forest's monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Alkem reverse-payment agreements, which Ascend willfully facilitated, were intended to and did prevent and/or delay generic competition to Bystolic and enabled Forest to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

257. Forest, Alkem and Ascend knowingly and intentionally conspired to maintain, enhance, and extend Forest's monopoly power in the relevant market.

258. Forest, Alkem and Ascend specifically intended that the reverse-payment agreements would maintain Forest's monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

259. Forest, Alkem and Ascend each committed at least one overt act in furtherance of the conspiracy.

260. As a direct, proximate, foreseeable, and intended result of Forest's, Alkem's and Ascend concerted monopolistic conduct, as alleged herein, Forest unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and

suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Alkem and Ascend would have launched Alkem's generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Alkem would have agreed upon earlier entry dates untainted by delay associated with the unlawful Alkem side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Alkem and Forest would also have applied to all earlier-settling Defendants.

XXI. CLAIM ELEVEN
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN INDCHEMIE AND FOREST)

261. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

262. At all relevant times prior to September 17, 2021, Forest possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Forest possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

263. Through the Indchemie reverse-payment agreements, Forest and Indchemie conspired to unlawfully maintain Forest's monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

264. The Indchemie reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

265. The goal, purpose and/or effect of the Indchemie reverse-payment agreements was to maintain, enhance, and extend Forest's monopoly power, in violation of Section 2 of the

Sherman Act, 15 U.S.C. § 2. The Indchemie reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

266. Forest and Indchemie knowingly and intentionally conspired to maintain, enhance, and extend Forest's monopoly power in the relevant market.

267. Forest and Indchemie specifically intended that the reverse-payment agreements would maintain Forest's monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

268. Forest and Indchemie each committed at least one overt act in furtherance of the conspiracy.

269. As a direct, proximate, foreseeable, and intended result of Forest's and Indchemie's concerted monopolistic conduct, as alleged herein, Forest unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Indchemie would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Indchemie would have agreed upon earlier entry dates untainted by delay associated with the unlawful Indchemie side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Indchemie and Forest would also have applied to all earlier-settling Defendants.

XXII. CLAIM TWELVE
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN GLENMARK AND FOREST)

270. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

271. At all relevant times prior to September 17, 2021, Forest possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Forest possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

272. Through the Glenmark reverse-payment agreements, Forest and Glenmark conspired to unlawfully maintain Forest's monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

273. The Glenmark reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

274. The goal, purpose and/or effect of the Glenmark reverse-payment agreements was to maintain, enhance, and extend Forest's monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Glenmark reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Forest to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

275. Forest and Glenmark knowingly and intentionally conspired to maintain, enhance, and extend Forest's monopoly power in the relevant market.

276. Forest and Glenmark specifically intended that the reverse-payment agreements would maintain Forest's monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

277. Forest and Glenmark each committed at least one overt act in furtherance of the conspiracy.

278. As a direct, proximate, foreseeable, and intended result of Forest's and Glenmark concerted monopolistic conduct, as alleged herein, Forest unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge

damages as a result, as alleged herein. Specifically, without a reverse payment, Glenmark would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Glenmark would have agreed upon earlier entry dates untainted by delay associated with the unlawful Glenmark side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Glenmark and Forest would also have applied to all earlier-settling Defendants.

XXIII. CLAIM THIRTEEN
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN AMERIGEN AND FOREST)

279. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

280. At all relevant times prior to September 17, 2021, Forest possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Forest possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

281. Through the Amerigen reverse-payment agreements, Forest and Amerigen conspired to unlawfully maintain Forest's monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

282. The Amerigen reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

283. The goal, purpose and/or effect of the Amerigen reverse-payment agreements was to maintain, enhance, and extend Forest's monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Amerigen reverse-payment agreements were intended to and

did prevent and/or delay generic competition to Bystolic and enabled Forest to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

284. Forest and Amerigen knowingly and intentionally conspired to maintain, enhance, and extend Forest's monopoly power in the relevant market.

285. Forest and Amerigen specifically intended that the reverse-payment agreements would maintain Forest's monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

286. Forest and Amerigen each committed at least one overt act in furtherance of the conspiracy.

287. As a direct, proximate, foreseeable, and intended result of Forest's and Amerigen's concerted monopolistic conduct, as alleged herein, Forest unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Amerigen would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Amerigen would have agreed upon earlier entry dates untainted by delay associated with the unlawful Amerigen side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Amerigen and Forest would also have applied to all earlier-settling Defendants.

XXIV. CLAIM FOURTEEN
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN WATSON AND FOREST)

288. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

289. At all relevant times prior to September 17, 2021, Forest possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market.

Forest possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

290. Through the Watson reverse-payment agreements, Forest and Watson conspired to unlawfully maintain Forest's monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

291. The Watson reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

292. The goal, purpose and/or effect of the Watson reverse-payment agreements was to maintain, enhance, and extend Forest's monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Watson reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Forest to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

293. Forest and Watson knowingly and intentionally conspired to maintain, enhance, and extend Forest's monopoly power in the relevant market.

294. Forest and Watson specifically intended that the reverse-payment agreements would maintain Forest's monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

295. Forest and Watson each committed at least one overt act in furtherance of the conspiracy.

296. As a direct, proximate, foreseeable, and intended result of Forest's and Watson's concerted monopolistic conduct, as alleged herein, Forest unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse payment, Watson would have launched its generic version of Bystolic upon receiving final FDA approval (whether before

or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Watson would have agreed upon earlier entry dates untainted by delay associated with the unlawful Watson side-deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Watson and Forest would also have applied to all earlier-settling Defendants.

XXV. CLAIM FIFTEEN
DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTIONS 1 AND 2 OF THE SHERMAN ACT, AND SECTION 16 OF THE CLAYTON ACT, 15 U.S.C. §§ 1, 2, 26 (ALL DEFENDANTS)

297. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

298. Plaintiff seeks declaratory and injunctive relief under the federal antitrust laws.

299. The conduct of Defendants as described herein constitutes violations of Sections 1 and 2 of the Sherman Act.

300. Defendants each entered into conspiracies to unreasonably restrain trade and monopolize the market for Bystolic.

301. There are and were no legitimate, non-pretextual, procompetitive business justifications for each Defendant's conduct that outweigh their harmful effect.

302. As a direct and proximate result of each Defendant's anticompetitive conspiracy, as alleged herein, Plaintiff and the Class were harmed.

303. The goal, purpose and/or effect of each conspiracy was to prevent and/or delay generic competition for Bystolic and to permit Defendants to share in the monopoly profits from sales of branded Bystolic.

304. Plaintiff and the Class have been injured in their business or property by reason of each Defendant's antitrust violations. Their injury consists of paying higher prices for nebivolol HCl than they would have paid in the absence of those violations. These injuries will continue unless halted.

305. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that each Defendant's conduct constitutes a violation of §§ 1 and 2 of the Sherman Act.

306. Plaintiff and the Class further seek equitable and injunctive relief pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct the anticompetitive effects caused by each Defendant's unlawful conduct. Specifically, Plaintiff and the Class hereby seek a judgment:

a) Requiring specific performance by amending the challenged reverse payment agreements to permit each Defendant to launch its generic version of Bystolic immediately; and

b) Disgorging from each Defendant its ill-gotten gains from the challenged reverse payment agreements.

XXVI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, pray for judgment against all Defendants, jointly and severally, as follows:

1. That the Court determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare the Plaintiff as the representative of the Class;

2. That the Court require specific performance by amending the challenged reverse payment agreements to permit each Defendant to launch its generic version of Bystolic immediately;

3. That the Court enter joint and several judgments against each of the Defendants and in favor of Plaintiff and the proposed Class for the Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act;

4. That Plaintiff and all others similarly situated be awarded damages, in an amount to be determined at trial, including post-judgment interest, suffered by reason of Defendants' violations and that those damages be trebled in accordance with the law;

5. That each Defendant disgorge its ill-gotten gains obtained as a result of its acts;

6. That Plaintiff and the proposed Class be awarded reasonable attorneys' fees and costs as provided by law; and

7. Such other and further relief as the Court may deem just and proper.

XXVII. JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all claims and complaints in this Complaint so triable.

DATED: September 10, 2020

Respectfully submitted,

J M SMITH CORPORATION d/b/a/
SMITH DRUG COMPANY

By: *<u>/s/ Bruce E. Gerstein</u>*

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